

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Methodology of the BRodalumab Assessment of Hazards: A Multicentre observational Safety (BRAHMS) study
<b>AUTHORS</b>	Reilev, Mette; Jensen, Peter Bjødstrup; Ranch, Lise Skov; Egeberg, A; Furu, Kari; Gembert, Karin; Hagg, David; Haug, Ulrike; Karlstad, Øystein; Reutfors, Johan; Schäfer, Wiebke; Schwartz, Sarina; Smits, Elisabeth; Holthius, Emily; Herings, Ron; Trifirò, Gianluca; Kirchmayer, Ursula; Rosa, Alessandro Cesare; Belleudi, Valeria; Gini, Rosa; Støvring, Henrik; Hallas, Jesper

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Lebwohl, Mark Icahn School of Medicine at Mount Sinai
<b>REVIEW RETURNED</b>	11-Jul-2022

<b>GENERAL COMMENTS</b>	making this more clinically relevant rather than solely a description of methodology, years after the introduction of brodalumab to the market, would make this more interesting to readers.
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<b>REVIEWER</b>	Asawanonda, Pravit Chulalongkorn University
<b>REVIEW RETURNED</b>	08-Oct-2022

<b>GENERAL COMMENTS</b>	This is a very ambitious and important study. With such long span of time, factors affecting outcomes must be weighed with great attention.
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Mark Lebwohl, Icahn School of Medicine at Mount Sinai

Comments to the Author:

making this more clinically relevant rather than solely a description of methodology, years after the introduction of brodalumab to the market, would make this more interesting to readers.

Response: Thank you for your comment. However, we believe that a comprehensive description of the methodology is within the scope of a protocol paper describing a post-authorization study required by the Committee for Medicinal Products for Human Use (CHMP). Clinically relevant issues will be investigated and discussed in future publications by the BRAHMS study group.

Manuscript revision: none

Reviewer: 2

Dr. Pravit Asawanonda, Chulalongkorn University

Comments to the Author:

This is a very ambitious and important study. With such long span of time, factors affecting outcomes must be weighed with great attention.

Response: Thank you for your comment. We agree that factors affecting outcomes must be weighed with great attention during such a long study period. To this end, we are to monitor e.g., the distribution of a large number of covariates, incidence rates and persistence to use of brodalumab and active comparators, length of treatment episodes etc. at the time of the interim report in 2023 as well as once more in an internal report before submitting the final report in 2030. Investigators meet regularly to address intervening changes in knowledge base, clinical practice, coding practice, data infrastructure etc.

Manuscript revision: none